DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
Facsimile: 504-253-4520

August 30, 2001

WARNING LETTER NO. 2001-NOL-53

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Noy Paul Phangnivong, President
Laomerica Seafood Inc.
14580 Saint Michael Street
Coden, Alabama 36523

Dear Mr. Phangnivong:

We inspected your firm, located at 14580 Saint Michael Street, Coden, Alabama, during July 23-26, 2001, and found that you have serious deviations from the seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123), and the Current Good Manufacturing Practice (CGMP) in manufacturing, packing, or holding food for human consumption, 21 CFR 110. These deviations cause your fresh, picked, ready-to-eat crabmeat, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

- You must fully implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of recording the actual cooking time at the cooking critical control point (CCP) as listed in your HACCP plan entitled Blue Crab Meat.

- You must take appropriate corrective action when a deviation from a critical limit occurs to comply with 21 CFR 123.7(a). However, your firm did not take a corrective action to control pathogen growth when you cooked the third batch of crabs for [redacted] thus deviating from your critical limit of [redacted] at the cooking CCP on July 24, 2001.

- You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan entitled Blue Crab Meat lists a critical limit, accumulative time only, at the backing, picking, and packing CCPs that is not adequate to control pathogen growth. Your firm does not monitor the temperature of the cooked crabs during the backing, picking, and packing CCPs.

- You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor the prevention of cross-contamination from insanitary objects to food as evidenced by unsanitized, rusty, steel hooks routinely contacting cooked crabs in the cooking basket.

In addition, the investigator documented numerous insanitary conditions that cause the crabmeat you manufacture to be adulterated within the meaning of Section 402(a)(4) of the Act.

The deviations were as follows:

- Employees working in direct contact with food and food-contact surfaces did not take necessary precautions to protect against contamination of those items with microorganisms or foreign substances. For example, they contacted insanitary equipment and then handled cooked crabs without washing or sanitizing their hands.

- Food processing equipment is not maintained in a sanitary condition to prevent food from becoming adulterated within the meaning of the Act. For example, the [redacted] used to wash backed, cooked crabs contained yellow and brownish residue from previous operations. In addition, the employees used etched handled knives encrusted with black residues during picking operations.

- The inspection found that cleaning and sanitizing utensils and equipment are not conducted in a manner that protects food and food-contact surfaces from contamination. For example, the concentration of chlorine (greater than 200 PPM) is unsafe for food-processing equipment and utensils.

- You have not taken effective measures to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. For example, numerous flies were observed landing on cooked crabs, the packing table, the picking table, ice used to cool the crabs, and other potential sources of contaminants.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

We are aware that you promised to correct the deviations that were brought to your attention during the inspection. You should notify this office in writing, within 15 working days of receipt of this letter, of the specific actions you are taking to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. You may wish to include in your response documentation such as your revised HACCP plan and copies of temperature monitoring records or other useful information that would assist us in evaluating your corrections. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time by which the corrections will be completed.

Send your reply to the U.S. Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4519.

Sincerely,

Patricia K. Schafer

Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483